

FDA/FCC Public Meeting: Converged Communications and Health Care  
Devices Impact on Regulation

July 26-27, 2010

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**Session 3: Healthcare Provider, Clinician & Patient Perspective**

Emerging Needs for Healthcare  
Environments of the Future

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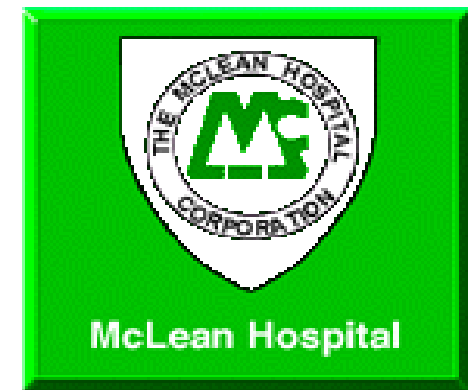
BRIGHAM AND  
WOMEN'S HOSPITAL



MASSACHUSETTS  
GENERAL HOSPITAL



Faulkner Hospital



Spaulding Rehabilitation Hospital

# Modern clinical environments are crowded with essential medical devices



Most have distributed components

-Wired => wireless

-Integration increasing





**ICU – most devices not networked but should be**



## Forward-area Operating Room in Iraq

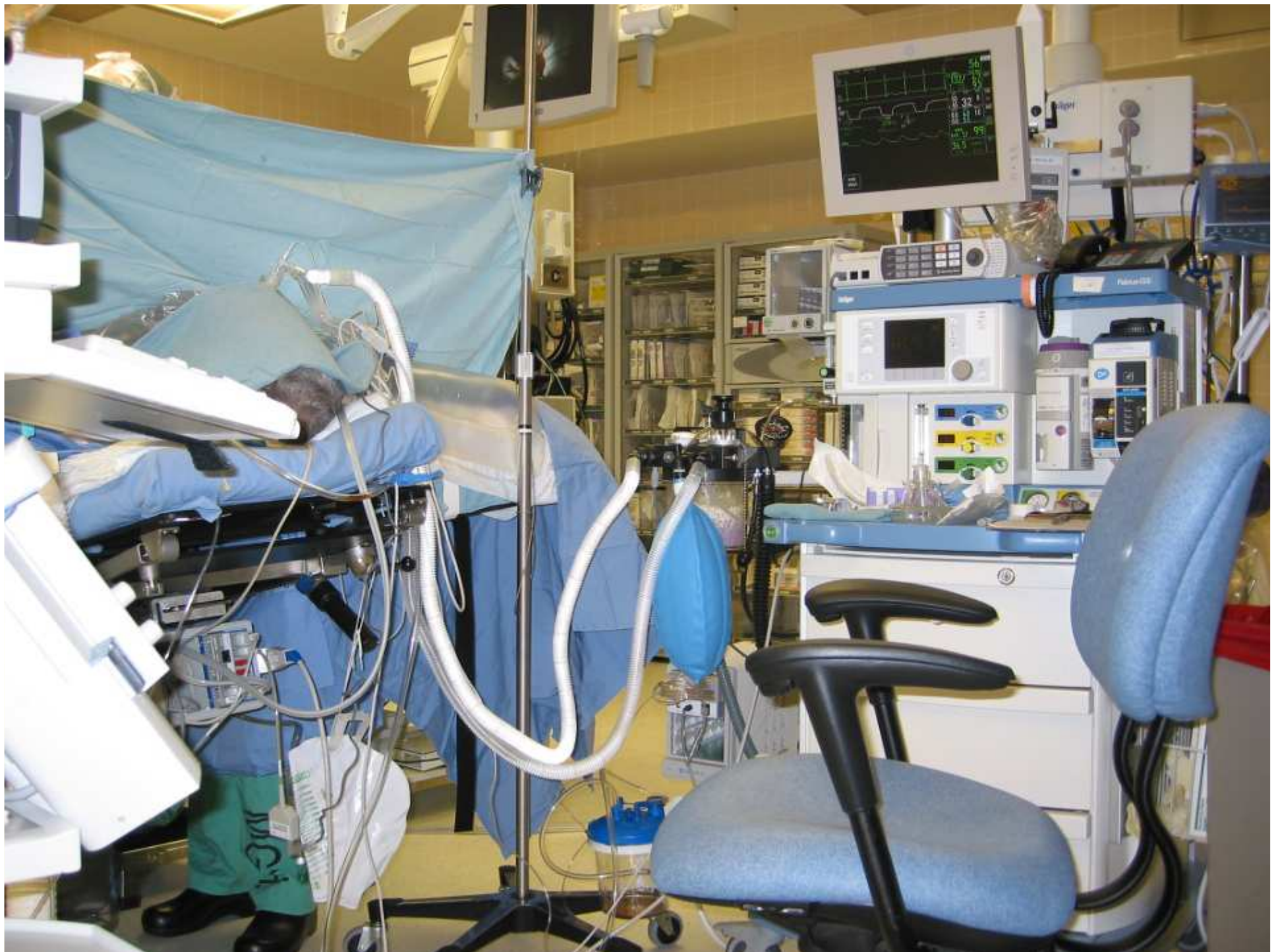


Networking with fixed,  
wired, infrastructure isn't  
practical

## Critical Care Air Transport









# MALIGNANT SPAGHETTI

A Symposium on  
Wireless Technologies  
in Hospital Health Care

Friday  
November 14, 2008  
9 a.m. to 5 p.m.

Polytechnic Institute  
of New York University  
The Dibner Library Building  
Five MetroTech Center  
Brooklyn, NY

Presented by  
The Wireless Internet Center for  
Advanced Technology (WICAT),  
The Center for Advanced Technology  
in Telecommunications (CATT)  
and The Othmer Institute for  
Disciplinary Studies.

Advances in medical technology have alleviated the need for patients to remain tethered to a serpentine connection of diagnostic equipment. In the past, these cables and wires formed a "malignant spaghetti"—and the only means of monitoring patient progress in and out of the operating room.

This one-day symposium will identify and explore existing and future technologies for the wireless hospital in areas such as patient monitoring devices and tracking and networking medical equipment. Experts from academia, industry, government, hospitals, and medical schools will discuss progress and challenges in the design and deployment of wireless systems for health care.

Registration and directions online at <http://wirelesshealth.poly.edu>

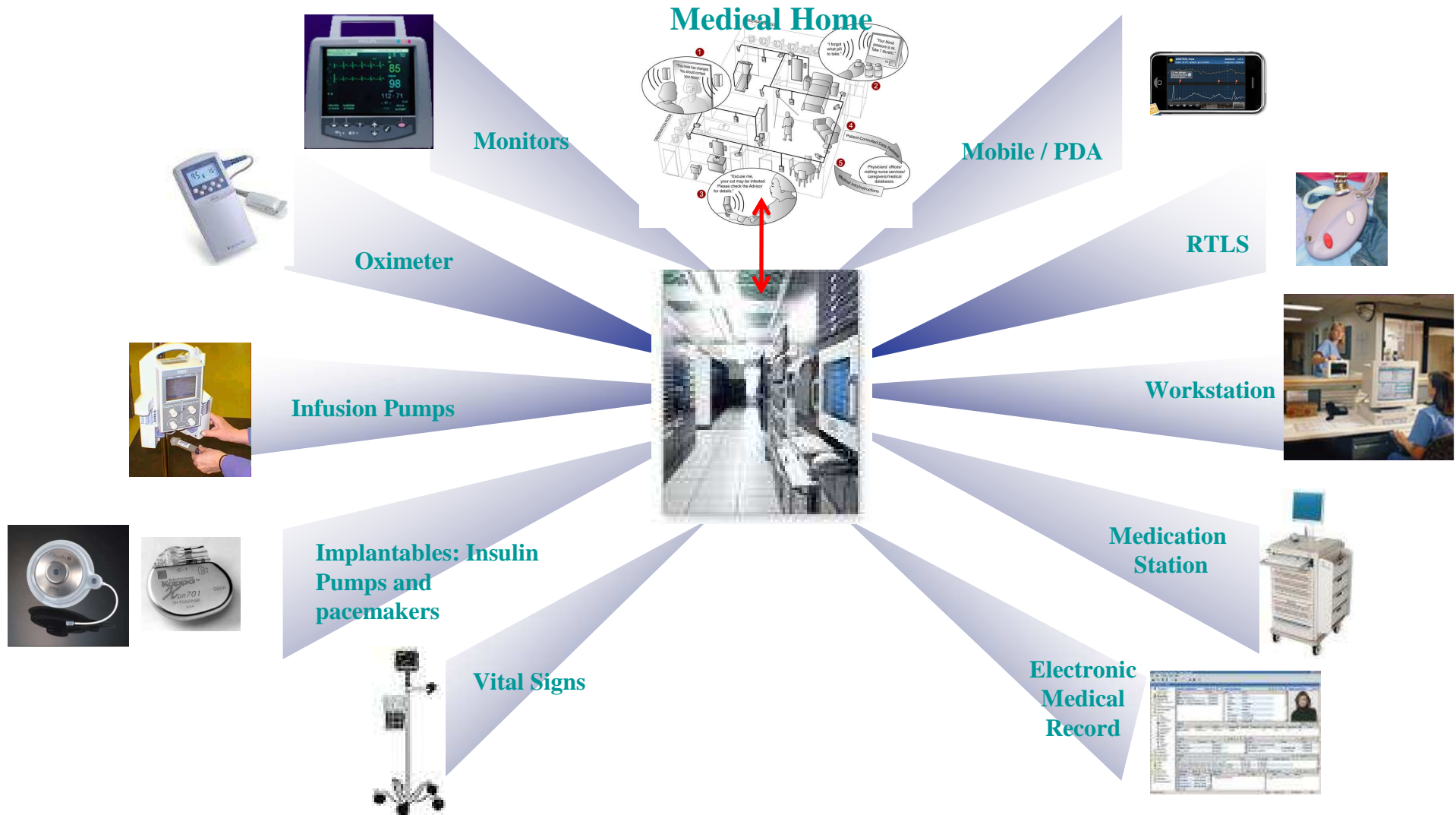
## “Get rid of the wires” is #1 clinician request

Wires create:

- Workflow barriers
- Hazards (falls, pull out IVs)
- Infection reservoir



# Stationary & Wired -> wireless & mobile



PHS – 20 devices/AP (max ~ 25)



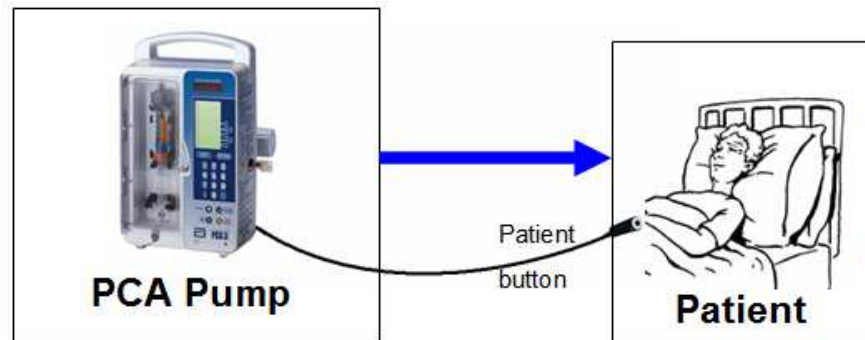
## Enhanced system capabilities are required to:

- Acquire healthcare data comprehensively
- Support distributed healthcare workers in managing high-acuity patients
- Add error-resistance to patient care
- Enable compliance with data security, integrity, and privacy requirements
- Manage the connected devices

*These needs are present across continuum of high-acuity healthcare: hospital, home, transport, etc.*

# Use Case Example: IV PCA System 1/2

PCA = Patient-Controlled Analgesia with IV pain medication  
For patient in pain after surgery/trauma



Typically today:

*Nurse verifies order in chart, obtains medication from pharmacy,  
loads medication in IV pump*

*Nurse programs pump-response to button press*

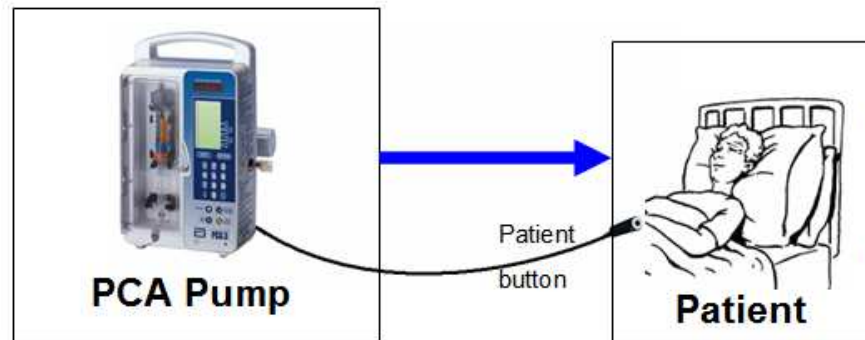
*Nurse visits room to check on patient's pain level, vital signs, and  
to detect life-threatening medication side effects*

***Current approach is fraught with potential for errors and patient  
injury***



# Use Case Example: IV PCA System 2/2

IV Pumps:  
~ 1M nationally  
25% wireless (limited  
connectivity)



Needed but not currently available:

*Medication in IV pump = order in EMR (requires remote programming or checking)*

*Dose from button press = dosage prescribed in EMR (same)*

*Status of pump => monitored by nurse*

*Patient's vital signs = monitored by nurse and by decision support/alarm system*

*Patient respiration depressed => stop pump*

*Pump medication/fluid levels => monitored by pharmacy*

***All of these device-device-EMR wireless data connections must be reliable, secure, and “real time” (seconds to minutes)***

# Policy Drivers

- Federal Policy
- Clinical Societies
- Regulatory



**U.S. Department of Health and Human Services**  
**Office of the National Coordinator for Health Information Technology**



**Common Device Connectivity**  
**AHIC Extension/Gap**

December 31, 2008

# Common Device Connectivity (CDC)

- HHS Office of National Coordinator for HIT  
Common Device Connectivity AHIC  
Extension/Gap Report:

“Therefore, the requirements for 2009 Common Device Connectivity Extension/Gap can be summarized as ... the ability to communicate high-acuity and inpatient multi and single parameter device information to and from an EHR and other specialized clinical information systems via direct network connections and wireless networking within an organization.”

Published December 2008  
(includes use cases)



## HITSP Device Connectivity Technical Note

HITSP/TN905



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Consumer Perspective Technical Committee

January 2010

“Though there are numerous technologies and standards for wireless networking, major issues remain in their utilization within healthcare contexts, especially given the need to maintain safe, effective and secure connections for life critical data flows. This gap needs to be addressed in order to support wireless networking in a heterogeneous environment.” (page 59)



# NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88

Circulation 80,350

Winter 2006-2007

## Dangers of Postoperative Opioids

*APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications*

“A particularly attractive feature may be the ability to automatically terminate or reduce PCA ... infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.

It is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner.”



RESOLVED, That our American Medical Association believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind ... ”

as of July 2009:

*Anesthesia Patient Safety Foundation  
Society for Technology in Anesthesia  
Society of American Gastrointestinal Endoscopic Surgeons*

*American Medical Association  
World Federation of Societies of Anesthesiologists  
American Society of Anesthesiologists  
Massachusetts Medical Society*

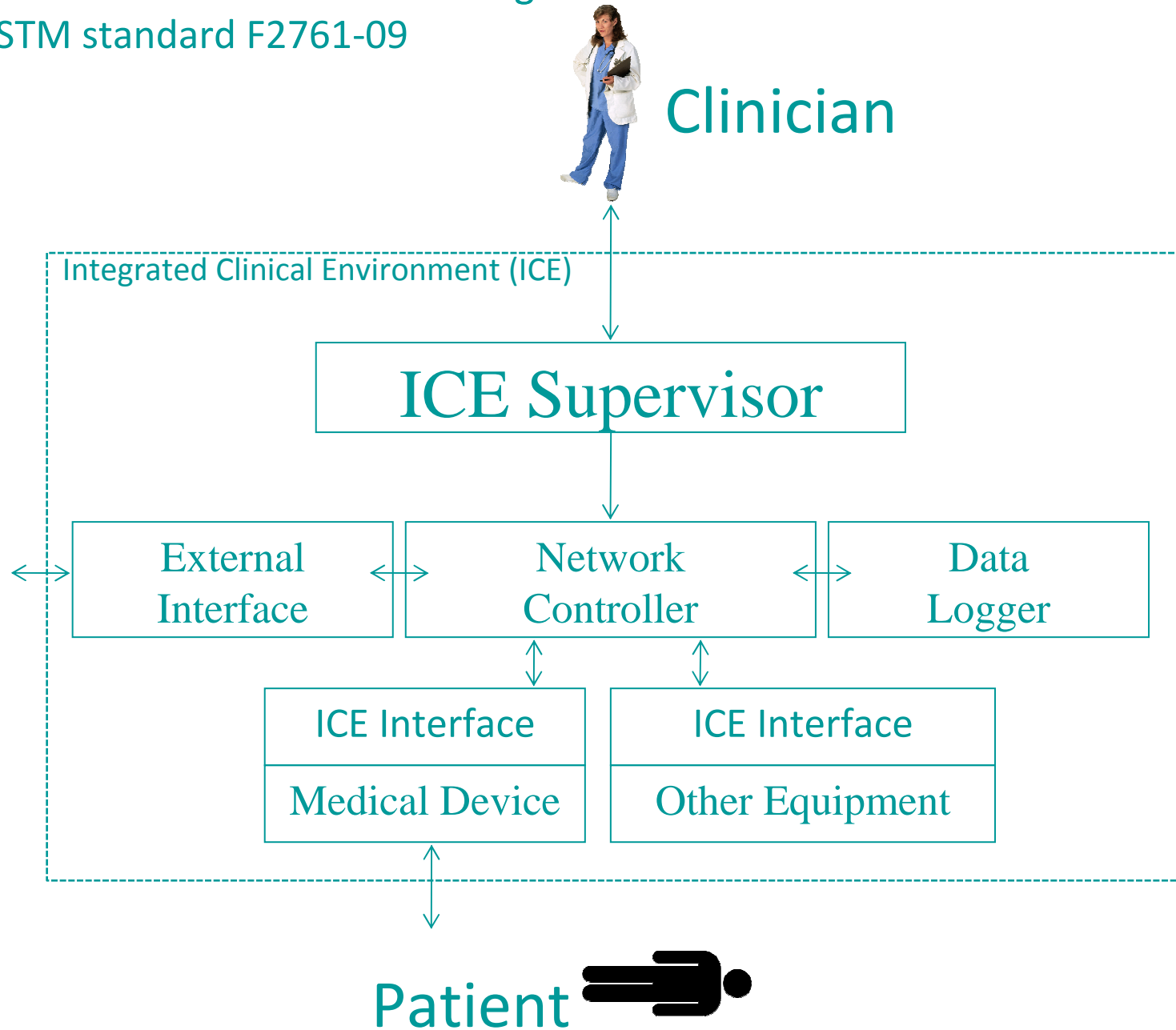


# Standard for the “Integrated Clinical Environment” ASTM F2761-09

“Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model”

# Functional Elements of the Integrated Clinical Environment

ASTM standard F2761-09



# Scope of ASTM ICE Part I

“This standard specifies general requirements... for integrating equipment to create a Integrated Clinical Environment (ICE) ...

This standard establishes requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices.”

# Examples of ICE Functions

- ICE functions:
  - Provide safety interlocks
  - Integrate and distribute alarm conditions to clinicians
  - Provide context-aware clinical decision support
  - Set variables of other medical devices, per context-appropriate rules in order to manage their operation (e.g. change blood pressure cuff cycle interval, change infusion rate)
  - Assess the readiness of medical devices in a clinical environment to support specified functions or clinical workflow
  - Record device-device communication for forensic analysis by healthcare institution



# Summary: emerging wireless needs for healthcare environments of the future

- Anticipate dramatic increase in number of wireless devices and device-data bandwidth requirements
  - ◆ 15-20x increase in 5 years (not considering complete RTLS)
- Reliable, interoperable, connectivity to build systems of heterogeneous devices to improve patient care and workflow
  - ◆ Efficient pathway to implement end-to-end security
  - ◆ Accommodate varying bandwidth requirements in system
- Data and tools to specify, evaluate and install equipment that will meet data quality & integrity requirements, regulations, and standards.
  - ◆ Assess performance and mitigate clinical risks
  - ◆ Wireless configuration management tools

# Thank you

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